

APPENDIX A

Drug	Goal of the REMS program	How this REMS is different from mifepristone REMS
Letairis (ambrisentan)	“mitigate the risk of embryo-fetal toxicity”	“To support REMS Program operations, Ambrisentan Applicants must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 7-8)
Tracleer (bosentan)	“mitigate the risks of hepatotoxicity and embryo-fetal toxicity”	“To support REMS Program operations, Bosentan Applicants must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 7-8)
Camzyos (mavacamten)	“mitigate the risk of heart failure due to systolic dysfunction”	“To support REMS operations, Bristol-Myers Squibb Company must: . . . <i>Provide certified pharmacies access to the database of certified healthcare providers and enrolled patients.</i> ” (p. 5-6)
Caprelsa (vandetanib)	“mitigate the serious risks of QT prolongation, Torsades de pointes, and sudden death”	“Genzyme must maintain a secure, validated, interactive, web-based database of all enrolled entities (prescribers, pharmacies, and distributors). . . . <i>Certified pharmacies can access the database to verify prescriber enrollment status as required by the REMS.</i> ” (p. 3)
Clozaril (clozapine)	“mitigate the risk of severe neutropenia”	“To support REMS program operations, Clozapine Applicants must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 7-8)
Fazaclo ODT (clozapine)	Same as Clozaril (clozapine)	<i>Id.</i>
Versacloz (clozapine)	Same as Clozaril (clozapine)	<i>Id.</i>
Empaveli (pegcetacoplan)	“mitigate the occurrence and morbidity associated with encapsulated bacteria infections”	“To support REMS Program operations, Apellis Pharmaceuticals, Inc. must: . . . <i>Provide certified pharmacies access to the database of certified prescribers.</i> ” (p. 3-4)

<u>Filspari (sparsentan)</u>	“mitigate the risks of hepatotoxicity and embryo-fetal toxicity”	“To support REMS operations, Traverre Therapeutics, Inc. must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 8-9)
<u>Fintepla (fenfluramine hydrochloride)</u>	“mitigate the risk of valvular heart disease and pulmonary arterial hypertension”	“To support REMS Program operations, Zogenix, Inc. must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 5-6)
<u>Absorica (isotretinoin)</u>	“prevent fetal exposure to isotretinoin”	“To support REMS Program operations, Isotretinoin Applicants must: . . . <i>Provide pharmacies access to the database of enrolled patients and certified prescribers.</i> ” (p. 5-6)
Absorica LD (isotretinoin)	Same as <u>Absorica (isotretinoin)</u>	<i>Id.</i>
<u>Juxtapid (lomitapide)</u>	“mitigate the risk of hepatotoxicity”	“To support REMS Program operations, Amryt Pharmaceuticals DAC must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 4)
<u>Jynarque (tolvaptan)</u>	“mitigate the risk of serious and potentially fatal liver injury”	“To support REMS Program operations, Otsuka Pharmaceutical Company, Ltd must . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 6-7)
<u>Lemtrada (alemtuzumab)</u>	“mitigate the risks of autoimmune conditions, infusion reactions, stroke, and malignancies”	“To support REMS Program operations, Genzyme must: . . . <i>Provide certified pharmacies and certified healthcare facilities access to the database of certified prescribers and enrolled patients.</i> ” (p. 7)
<u>Revlimid (lenalidomide)</u>	“prevent the risk of embryo-fetal exposure”	“To support REMS Program operations, Lenalidomide Applicants must: . . . Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the REMS Program. . . . <i>Provide certified pharmacies access to the REMS system.</i> ” (p. 9)

<u>Opsumit (macitentan)</u>	“mitigate the risk of embryo-fetal toxicity”	“To support the REMS operations, Macitentan REMS Applicants must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 6-7)
<u>Myalept (metreleptin)</u>	“mitigate (1) the risks of serious adverse sequelae (such as severe infections, excessive weight gain, glucose intolerance, diabetes mellitus) due to the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or Myalept, and (2) the risk of lymphoma”	“To support REMS Program operations, Amryt Pharmaceuticals DAC must: . . . <i>Provide certified pharmacies access to the database of certified prescribers.</i> ” (p. 3-4)
<u>Natpara (parathyroid hormone)</u>	“mitigate the potential risk of osteosarcoma”	“To support REMS Program operations, Shire-NPS Pharmaceuticals, Inc. must: <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 3-4)
<u>Palforzia (peanut (Arachis hyogaea) allergen powder dnfp)</u>	“mitigate the risk of anaphylaxis”	“To support REMS Program operations, Aimmune Therapeutics, Inc. must: <i>Provide certified pharmacies access to the database of certified prescribers, healthcare settings and enrolled patients.</i> ” (p. 6)
<u>Palynziq (pegvaliase- pqpz)</u>	“mitigate the risk of anaphylaxis”	“To support REMS Program operations, BioMarin must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 4)
<u>Pomalyst (pomalidomide)</u>	“prevent the risk of embryo-fetal exposure”	“To support REMS Program operations, Celgene must: “Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the REMS Program. . . . <i>Provide certified pharmacies access to the REMS system.</i> ” (p. 8-9)

<u>Probuphine (buprenorphine hydrochloride)</u>	“mitigate the risk of complications of migration, protrusion, expulsion and nerve damage associated with the insertion and removal of Probuphine”	“To support REMS Program operations, Titan Pharmaceuticals, Inc. must: . . . Establish and maintain a validated, secure database of all REMS participants who are certified in the Probuphine REMS Program. . . . <i>Provide certified prescribers, certified healthcare providers who insert Probuphine, certified pharmacies, and wholesalers-distributors access to the database of these participants.</i> ” (p. 5-6)
<u>Qsymia (phentermine and topiramate)</u>	mitigate the “increased risk of congenital malformations, specifically orofacial clefts, in infants exposed to Qsymia during the first trimester of pregnancy”	“To support REMS Program operations, VIVUS LLC must: . . . <i>Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Qsymia REMS Program.</i> ” (p. 2)
<u>Adempas (riociguat)</u>	“mitigate the risk of embryo-fetal toxicity”	“To support REMS Program operations, Riociguat Applicants must: <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 7-8)
<u>Siliq (brodalumab)</u>	“mitigate the observed risk of suicidal ideation and behavior, including completed suicides”	“To support REMS Program operations, Bausch Health US, LLC must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 3-4)
<u>Spravato (esketamine)</u>	“mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO administration, and abuse and misuse of SPRAVATO”	“To support REMS Program operations, Janssen Pharmaceuticals, Inc. must: . . . <i>Provide certified pharmacies access to the database of certified healthcare settings.</i> ” (p. 5-6)
<u>Sublocade (buprenorphine extended- release)</u>	“mitigate the risk of serious harm or death that could result from intravenous self-administration”	“SUBLOCADE is dispensed directly to a healthcare provider,” not to a patient. (p. 1) “To support REMS Program operations, Indivior must: Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the SUBLOCADE REMS.” (p. 3)

<u>Tecvayli (teclistamab-cqyv)</u>	“mitigate the risk of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)”	“To support REMS operations, Janssen Biotech, Inc. must: . . . <i>Provide certified pharmacies and healthcare settings access to the database of certified prescribers.</i> ” (p. 4-5)
<u>Tegsedi (inotersen)</u>	“mitigate the risk of serious bleeding with severe thrombocytopenia and the risk of glomerulonephritis”	“To support REMS operations, Akcea Therapeutics must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 5-6)
<u>Thalomid (thalidomide)</u>	“prevent the risk of embryo-fetal exposure”	“To support REMS Program operations, Celgene must: . . . Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the REMS Program. . . . <i>Provide certified pharmacies access to the REMS system.</i> ” (p. 8-9)
<u>Actiq (fentanyl citrate)</u>	“[m]itigate the risk of overdose”	“To support REMS program operations, TIRF Applicants must: . . . <i>Provide certified outpatient pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 7-8)
Fentora (fentanyl citrate)	Same as <u>Actiq (fentanyl citrate)</u>	<i>Id.</i>
Lazanda (fentanyl citrate)	Same as <u>Actiq (fentanyl citrate)</u>	<i>Id.</i>
Onsolis (fentanyl citrate)	Same as <u>Actiq (fentanyl citrate)</u>	<i>Id.</i>
Subsys (fentanyl)	Same as <u>Actiq (fentanyl citrate)</u>	<i>Id.</i>
<u>Turalio (pexdartinib)</u>	“mitigate the risk of serious and potentially fatal liver injury”	“To support REMS operations, Daiichi Sankyo, Inc. must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 4-5)
<u>Tysabri (natalizumab)</u>	mitigate “the risk of progressive multifocal leukoencephalopathy (PML)”	Certified pharmacies may dispense only to authorized infusion sites, not to patients. (p. 3) “To support REMS Program operations, Biogen must: . . . <i>Provide certified pharmacies access to the database of certified infusion sites and enrolled patients.</i> ” (p. 5)

<u>Sabril (vigabatrin)</u>	“mitigate the risk of vision loss”	“To support REMS Program operations, the Vigabatrin Applicants must: . . . <i>Provide certified pharmacies access to the database of certified prescribers and enrolled patients.</i> ” (p. 5)
<u>Xiaflex (collagenase clostridium histolyticum)</u>	“mitigate the risks of corporal rupture (penile fracture) and other serious penile injuries”	“To support REMS Program operations, Endo Pharmaceuticals, Inc. must: . . . <i>Provide certified pharmacies and healthcare settings access to the database of certified prescribers.</i> ” (p. 3-4)
<u>Xyrem/Xywav (calcium, magnesium, potassium, and sodium oxybates)</u>	“mitigate the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion”	“To support REMS Program operations, Jazz Pharmaceuticals must: . . . <i>Provide the certified pharmacy access to the database of certified prescribers and enrolled patients.</i> ” (p. 7-8)
<u>Zulresso (brexanolone)</u>	“mitigate the risk of serious harm resulting from excessive sedation and sudden loss of consciousness during the ZULRESSO infusion”	Certified pharmacies may dispense only to a certified healthcare setting, not to a patient. (p. 4) “To support REMS Program operations, Sage Therapeutics, Inc. must: . . . <i>Provide certified pharmacies access to the database of certified healthcare settings and authorized wholesalers-distributors.</i> ” (p. 5-6)
<u>Zyprexa Relprevv (olanzapine)</u>	“mitigate the risk of negative outcomes associated with Zyprexa Relprevv post-injection delirium/sedation syndrome (PDSS)”	Zyprexa Relprevv “can only be dispensed for use in certain health-care settings that have ready access to emergency response services,” not to patients. (p. 4) “Lilly will ensure that certified dispensers will verify that each patient is eligible to receive Zyprexa Relprevv prior to dispensing each prescription/ refill of Zyprexa Relprevv <i>by accessing the Zyprexa Relprevv Patient Care Program and ensuring the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry and the prescriber is certified.</i> ” (p. 5)